

## PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

|  |   |
|--|---|
| Date of mailing (day/month/year)<br>30 July 2001 (30.07.01)              | To:<br><br>Commissioner<br>US Department of Commerce<br>United States Patent and Trademark<br>Office, PCT<br>2011 South Clark Place Room<br>CP2/5C24<br>Arlington, VA 22202<br>ETATS-UNIS D'AMERIQUE<br><br>in its capacity as elected Office |
| International application No.<br>PCT/JP00/06852                          | Applicant's or agent's file reference<br>P757PCT  |
| International filing date (day/month/year)<br>03 October 2000 (03.10.00) | Priority date (day/month/year)<br>18 October 1999 (18.10.99)  |
| Applicant<br>OHTOMO, Kazumi et al  |   |

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

17 April 2001 (17.04.01)

in a notice effecting later election filed with the International Bureau on:

\_\_\_\_\_

2. The election  was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

|  |  |
|--|--|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>.1211 Geneva 20, Switzerland<br><br>Facsimile No.: (41-22) 740.14.35 | Authorized officer<br><br>Maria Kirchner<br><br>Telephone No.: (41-22) 338.83.38 |
|--|--|

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
26 April 2001 (26.04.2001)

PCT

(10) International Publication Number  
**WO 01/28522 A3**

(51) International Patent Classification<sup>7</sup>: **A61K 9/127.** (74) Agents: KOTANI, Etsuji et al.: Nichimen Building 2nd Floor, 2-2, Nakanoshima 2-chome, Kita-ku, Osaka-shi, Osaka 530-0005 (JP).

(21) International Application Number: PCT/JP00/06852

(22) International Filing Date: 3 October 2000 (03.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
11/295834 18 October 1999 (18.10.1999) JP

(71) Applicant (for all designated States except US): FUJISAWA PHARMACEUTICAL CO., LTD. [JP/JP]: 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP).

(72) Inventors; and  
(75) Inventors/Applicants (for US only): OHTOMO, Kazumi [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP). KONNO, Hajime [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP). KASAI, Akihiro [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:  
— with international search report

(88) Date of publication of the international search report:  
10 May 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/28522 A3

(54) Title: METHOD FOR PRODUCING LIPOSOME PREPARATION

(57) Abstract: An object of the present invention is to provide a method for producing a liposome preparation having excellent rapid action and excellent redispersion into aqueous medium. The present invention provides a method for producing a liposome preparation by vacuum drying wherein liposome condensed solution, which is obtained by removing solvent from liposome solution, is subjected to vacuum drying without freezing while bubbling the condensed solution or after the condensed solution is bubbled.

## PENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br><b>P757PCT</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |   |
| International application No.<br><b>PCT/JP 00/06852</b> | International filing date ( <i>day/month/year</i> )<br><b>03/10/2000</b>  | (Earliest) Priority Date ( <i>day/month/year</i> )<br><b>18/10/1999</b> |
| Applicant<br><b>FUJISAWA PHARMACEUTICAL CO., LTD.</b>   |   |   |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2.  Certain claims were found unsearchable (See Box I).

3.  Unity of invention is lacking (see Box II).

4. With regard to the **title**,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

- as suggested by the applicant.
- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No

R 00/06852

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61K9/127 A61K31/436

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.   |
|------------|---|-------------------------|
| X          | WO 92 22298 A (WU GUANLI ; UNGER EVAN C (US)) 23 December 1992 (1992-12-23)<br>page 20, line 12 -page 21, line 2<br>examples 1,3<br>claims 1,2,28,45<br>---           | 1-3,5,6,<br>9,10,12     |
| X          | WO 86 01103 A (LIPOSOME CO INC)<br>27 February 1986 (1986-02-27)<br>page 8, line 1 - line 17<br>page 13, line 20 - line 26<br>example 1<br>claims 1,4,10,20,22<br>--- | 1,5,6,9,<br>10,12       |
| X          | US 4 532 130 A (DJORDJEVICH LJUBOMIR ET AL) 30 July 1985 (1985-07-30)<br>examples 1,3<br>claims 1,6,8,11<br>---   | 1,2,5,6,<br>9,12<br>-/- |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

19 July 2001

Date of mailing of the international search report

01/08/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Epskamp, S

## INTERNATIONAL SEARCH REPORT

International Application No

JP 00/06852

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| X          | <p>DATABASE WPI<br/>       Section Ch, Week 199505<br/>       Derwent Publications Ltd., London, GB;<br/>       Class B05, AN 1995-032407<br/>       XP002164972<br/>       &amp; JP 06 315623 A (CHIBA SEIFUN KK),<br/>       15 November 1994 (1994-11-15)<br/>       abstract</p> <p>---</p>                  | 1,5,6,9,<br>12        |
| X          | <p>EP 0 658 344 A (FUJISAWA PHARMACEUTICAL<br/>       CO) 21 June 1995 (1995-06-21)<br/>       page 6, line 54 - line 55<br/>       examples<br/>       claims</p> <p>&amp; WO 93 08802 A (FUJISAWA PHARMACEUTICAL<br/>       CO.) 13 May 1993 (1993-05-13)<br/>       cited in the application</p> <p>-----</p> | 12                    |

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/JP 00/06852

| Patent document cited in search report | Publication date | Patent family member(s)  | Publication date   |  |
|--|------------------|--|--|--|
| WO 9222298 A                           | 23-12-1992       | AU 667672 B<br>AU 2023892 A<br>CA 2110490 A<br>EP 0660714 A<br>JP 6508617 T<br>US 5469854 A<br>US 5580575 A<br>US 5585112 A<br>US 5542935 A<br>US 5773024 A<br>US 5733572 A<br>US 5922304 A<br>US 5705187 A<br>US 5715824 A<br>US 5770222 A<br>US 6088613 A<br>US 5656211 A<br>US 5853752 A<br>US 6146657 A<br>US 5935553 A<br>US 6039557 A<br>US 6071495 A  | 04-04-1996<br>12-01-1993<br>23-12-1992<br>05-07-1995<br>29-09-1994<br>28-11-1995<br>03-12-1996<br>17-12-1996<br>06-08-1996<br>30-06-1998<br>31-03-1998<br>13-07-1999<br>06-01-1998<br>10-02-1998<br>23-06-1998<br>11-07-2000<br>12-08-1997<br>29-12-1998<br>14-11-2000<br>10-08-1999<br>21-03-2000<br>06-06-2000   |  |
| -----                                  |                  |  |  |  |
| WO 8601103 A                           | 27-02-1986       | US 4880635 A<br>AT 96311 T<br>AT 96310 T<br>AT 149347 T<br>AT 149346 T<br>CA 1270197 A<br>CA 1270198 A<br>CA 1283604 A<br>CA 1294548 A<br>CA 1305054 A<br>DE 3587639 D<br>DE 3587639 T<br>DE 3587640 D<br>DE 3587640 T<br>DE 3588146 D<br>DE 3588146 T<br>DE 3588148 D<br>DE 3588148 T<br>EP 0191824 A<br>EP 0190315 A<br>EP 0562641 A<br>EP 0561424 A<br>ES 545955 D<br>ES 8701516 A<br>ES 552076 D<br>ES 8704755 A<br>HK 1007494 A<br>HK 1007501 A<br>IE 68686 B<br>IL 76010 A<br>JP 2847065 B<br>JP 9020652 A<br>JP 2574999 B<br>JP 7145041 A<br>JP 2572553 B | 14-11-1989<br>15-11-1993<br>15-11-1993<br>15-03-1997<br>15-03-1997<br>12-06-1990<br>12-06-1990<br>30-04-1991<br>21-01-1992<br>14-07-1992<br>02-12-1993<br>24-03-1994<br>02-12-1993<br>31-03-1994<br>10-04-1997<br>09-10-1997<br>10-04-1997<br>09-10-1997<br>27-08-1986<br>13-08-1986<br>29-09-1993<br>22-09-1993<br>01-12-1986<br>01-03-1987<br>16-04-1987<br>01-07-1987<br>16-04-1999<br>16-04-1999<br>10-07-1996<br>18-01-1990<br>13-01-1999<br>21-01-1997<br>22-01-1997<br>06-06-1995<br>16-01-1997 |  |

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/JP 00/06852

| Patent document cited in search report | Publication date | Patent family member(s) |       | Publication date |
|--|------------------|-------------------------|-------|------------------|
| WO 8601103 A                           |                  | JP 7165560 A            |       | 27-06-1995       |
|  |                  | JP 2572554 B            |       | 16-01-1997       |
|  |                  | JP 7145042 A            |       | 06-06-1995       |
|  |                  | JP 2579441 B            |       | 05-02-1997       |
|  |                  | JP 7145043 A            |       | 06-06-1995       |
|  |                  | JP 2579442 B            |       | 05-02-1997       |
|  |                  | JP 7145040 A            |       | 06-06-1995       |
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|  |                  | JP 62500101 T           |       | 16-01-1987       |
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|  |                  | JP 62500102 T           |       | 16-01-1987       |
|  |                  | PT 80926 A, B           |       | 01-09-1985       |
|  |                  | US 5578320 A            |       | 26-11-1996       |
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|  |                  | US 5077056 A            |       | 31-12-1991       |
| -----                                  | -----            | -----                   | ----- | -----            |
| US 4532130 A                           | 30-07-1985       | AU 8760682 A            |       | 02-02-1983       |
|  |                  | EP 0082877 A            |       | 06-07-1983       |
|  |                  | WO 8300089 A            |       | 20-01-1983       |
| -----                                  | -----            | -----                   | ----- | -----            |
| JP 6315623 A                           | 15-11-1994       | NONE                    |       |                  |
| -----                                  | -----            | -----                   | ----- | -----            |
| EP 0658344 A                           | 21-06-1995       | AT 188378 T             |       | 15-01-2000       |
|  |                  | DE 69230541 D           |       | 10-02-2000       |
|  |                  | DE 69230541 T           |       | 24-08-2000       |
|  |                  | DK 658344 T             |       | 17-04-2000       |
|  |                  | GR 3032319 T            |       | 27-04-2000       |
|  |                  | KR 253492 B             |       | 01-05-2000       |
|  |                  | CA 2122344 A            |       | 01-05-1993       |
|  |                  | ES 2140419 T            |       | 01-03-2000       |
|  |                  | WO 9308802 A            |       | 13-05-1993       |
|  |                  | US 5817333 A            |       | 06-10-1998       |
| -----                                  | -----            | -----                   | ----- | -----            |

## PATENT COOPERATION TREATY

PCT


**NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT**

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

KOTANI, Etsuji  
 Sumisei Naniwasuji Honmachi  
 Building 3-2,  
 Utsubohonmachi 2-chome  
 Nishi-ku, Osaka-shi  
 Osaka 550-0004  
 JAPON

|   |
|---|
| Date of mailing (day/month/year)<br>24 November 2000 (24.11.00) |
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|--|--|
| Applicant's or agent's file reference<br>P757PCT                     | <b>IMPORTANT NOTIFICATION</b>  |
| International application No.<br>PCT/JP00/06852                      | International filing date (day/month/year)<br>03-October-2000 (03.10.00) |
| International publication date (day/month/year)<br>Not yet published | Priority date (day/month/year)<br>18 October 1999 (18.10.99)             |
| Applicant<br>FUJISAWA PHARMACEUTICAL CO., LTD. et al                 |  |

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

| <u>Priority date</u>    | <u>Priority application No.</u> | <u>Country or regional Office<br/>or PCT receiving Office</u> | <u>Date of receipt<br/>of priority document</u> |
|-------------------------|---------------------------------|---|---|
| 18 Octo 1999 (18.10.99) | 11/295834                       | JP  | 17 Nove 2000 (17.11.00)                         |

|  |   |
|--|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No. (41-22) 740.14.35 | Authorized officer<br><br>Khemais BRAHMI<br><br>Telephone No. (41-22) 338.83.38 |
|--|---|

## PATENT COOPERATION TREATY

PCT

**NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES**

(PCT Rule 47.1(c), first sentence)

|  |  |   |  |
|--|--|---|--|
| Date of mailing (day/month/year)<br>26 April 2001 (26.04.01) |  | From the INTERNATIONAL BUREAU<br>To:<br>KOTANI, Etsuji<br>Nichimen Building 2nd Floor<br>2-2, Nakanoshima 2-chome<br>Kita-ku, Osaka-shi, Osaka 530-0005<br>JAPON<br> |  |
| Applicant's or agent's file reference<br>P757PCT             |  | <b>IMPORTANT NOTICE</b>   |  |
| International application No.<br>PCT/JP00/06852              | International filing date (day/month/year)<br>03 October 2000 (03.10.00) | Priority date (day/month/year)<br>18 October 1999 (18.10.99)  |  |
| Applicant<br>FUJISAWA PHARMACEUTICAL CO., LTD. et al         |  |   |  |

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AG,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,ES,  
FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,  
MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,  
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on  
26 April 2001 (26.04.01) under No. WO 01/28522

**REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)**

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

**REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))**

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

|  |   |
|--|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No. (41-22) 740.14.35 | Authorized officer<br><br>J. Zahra<br><br>Telephone No. (41-22) 338.83.38 |
|--|---|

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

|  |  |   |
|--|--|---|
| Applicant's or agent's file reference<br><br>P757PCT   | <b>FOR FURTHER ACTION</b>  | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No.<br><br>PCT/JP00/06852  | International filing date (day/month/year)<br><br>03/10/2000               | Priority date (day/month/year)<br><br>18/10/1999  |
| International Patent Classification (IPC) or national classification and IPC<br><br>A61K9/127  |  |   |
| <p>Applicant<br/><br/>FUJISAWA PHARMACEUTICAL CO., LTD.</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I    <input checked="" type="checkbox"/> Basis of the report</li> <li>II    <input type="checkbox"/> Priority</li> <li>III    <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV    <input type="checkbox"/> Lack of unity of invention</li> <li>V    <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI    <input type="checkbox"/> Certain documents cited</li> <li>VII    <input type="checkbox"/> Certain defects in the international application</li> <li>VIII    <input type="checkbox"/> Certain observations on the international application</li> </ul> |  |   |
| Date of submission of the demand<br><br>17/04/2001   | Date of completion of this report<br><br>06.02.2002                        |   |
| Name and mailing address of the international preliminary examining authority:<br><br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465   | Authorized officer<br><br>Lindner, A<br><br>Telephone No. +49 89 2399 8640 |   |



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/JP00/06852

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-34                   as originally filed

**Claims, No.:**

1-12                   as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description,       pages:
- the claims,           Nos.:
- the drawings,       sheets:

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/JP00/06852

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**6. Additional observations, if necessary:**

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N) Yes: Claims 1-11  
No: Claims 12

Inventive step (IS) Yes: Claims  
No: Claims 1-11

Industrial applicability (IA) Yes: Claims 1-12  
No: Claims

**2. Citations and explanations  
see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP00/06852

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: WO 92 22298 A (WU GUANLI ;UNGER EVAN C (US)) 23 December 1992 (1992-12-23)  
D2: WO 86 01103 A (LIPOSOME CO INC) 27 February 1986 (1986-02-27)  
D3: US-A-4 532 130 (DJORDJEVICH LJUBOMIR ET AL) 30 July 1985 (1985-07-30)  
D4: DATABASE WPI Section Ch, Week 199505 Derwent Publications Ltd., London, GB; Class B05, AN 1995-032407 XP002164972 & JP 06 315623 A (CHIBA SEIFUN KK), 15 November 1994 (1994-11-15)

2. All of documents D1 to D4 relate to a method for producing liposomes wherein a liposome solution is subjected to vacuum drying without freezing (D1: p. 20, l. 12 - p. 21, l. 2; examples 1-3; claims; D2: p. 8, l. 1-17; p. 13, l. 20-26; example 1; claims 1, 4, 10, 20, 22; D3: examples 1 and 3; claims 1, 6, 8, 11; D4; whole document). The step of first removing solvent separately is not specifically disclosed in D1-D4.
3. The subject-matter of claim 12 is not novel over any of documents D1-D4 (Article 33(2) PCT). In this context it is noted that the separate removal of solvent does not have any influence on the final product, all the more so as no lipid or solvent concentrations are given.
4. The subject-matter of claims 1-11 does not involve an inventive step over any of documents D1-D4. Thus, the method as claimed in present claim 1 encompasses the situation that a very diluted liposome solution is first concentrated for practical reasons before it is subjected to vacuum drying. Nothing inventive can be seen in such a step.